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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,542	12/11/2003	Stephen C. Wardlaw	5169-0011-1-1	7739
7590 01/11/2005 McCormick, Paulding & Huber LLP City Place II 185 Asylum Street Hartford, CT 06103-3402			EXAMINER BHAT, ADITYA S	
			ART UNIT 2863	PAPER NUMBER

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/733,542	<b>Applicant(s)</b> WARDLAW ET AL.	
	<b>Examiner</b> Aditya S Bhat	<b>Art Unit</b> 2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-10,13,14 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-10,13,14 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/11/2003</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-10, 13-14 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (USPN 4,858,154).

With regards to claim 1, Anderson et al. (USPN 4,858,154) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument; (Col. 3, lines 16-25)

directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the one or more quality control specimens; (Col. 4 lines 25-35)

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; (Col. 3 lines 1-15),

evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument; and (Col. 3 lines 55-57)

providing notice to an operator regarding the functional status of the analytical instrument. (Col. 3, lines 17-20).

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With regards to claim 20, Anderson et al. (USPN 4,858,154) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument (Col. 3, lines 16-25);

directly or indirectly communicating control data to the analytical instrument, wherein the control data includes acceptable operating standards (Col. 4 lines 25-35);

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data (Col. 3 lines 1-15);

evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument (Col. 3, lines 55-57); and

providing notice to the operator regarding the functional status of the analytical instrument (Col. 3, lines 17-20).

With regards to claim 21, Anderson et al. (USPN 4,858,154) teaches a quality control system for analytical instruments, said system comprising:

one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen (Col. 3 lines 1-25);

an analytical instrument, having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values (Col. 4, lines 26-35):

means for evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values to determine a functional status of the analytical instrument (Col. 5, lines 1-6); and

means for notifying an operator regarding the functional status of the analytical instrument (Col. 3, lines 17-20).

With regards to claim 2, Anderson et al. (USPN 4,858,154) teaches the evaluation being performed without operator input (Col. 8, lines 37-45).

With regards to claim 3, Anderson et al. (USPN 4,858,154) teaches the evaluation is performed using routines preprogrammed within the analytical instrument (Col. 8, lines 37-45).

With regards to claim 4, Anderson et al. (USPN 4,858,154) teaches the evaluation is performed using a remotely located instrument independent of the analytical instrument (Col. 8, lines 37-45).

With regards to claim 5, Anderson et al. (USPN 4,858,154) teaches the step of evaluating the instrument analysis data includes a comparison of the characteristic values for the one or more quality control specimens and one or more characteristic values created within the instrument analysis data (Col. 5, lines 1-5).

With regards to claim 8 Anderson et al. (USPN 4,858,154) teaches the control data is communicated to the analytical instrument from a remote source via an electronic communications connection (Col. 8, lines 37-45).

With regards to claim 9, Anderson et al. (USPN 4,858,154) teaches communicating to the analytical instrument that the quality control specimen is for quality control purposes (Col. 3, lines 50-67).

With regards to claim 10, Anderson et al. (USPN 4,858,154) teaches communicating to the analytical instrument that the quality control specimen is for quality control purposes is performed without operator input (Col. 8, lines 37-45).

With regards to claim 18, Anderson et al. (USPN 4,858,154) teaches the step of automatically providing notice to a service provider that a scheduled quality control procedure has not been performed within a predetermined period of time (Col.8, lines 37-45).

With regards to claim 19 Anderson et al. (USPN 4,858,154) teaches the step of providing a standardized utilizing quality control procedures (Col. 5, lines 4-6).

With regards to claim 22, Anderson et al. (USPN 4,858,154) teaches evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values does not require input from an operator (Col.8, lines 37-40).

With regards to claim 23 Anderson et al. (USPN 4,858,154) teaches a standardized identifier displayed with the system that identifies the system as using quality control procedures (Col. 3, lines 3-15).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 19 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 9 of patent 6,748,337. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the claims in the current application are encompassed in the previous application. The latter pending application encompasses the same process as the pending application and is a slightly broader version of the previous application. (Underlined portions below, show the differences in the process)

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 6 (10/733542)	Claim 6 (6,748,337)
1. A method for providing quality control in an analytical instrument, said method comprising the steps of: sending one or more quality control specimens to a operator of the analytical instrument;	1. A method for providing quality control in an analytical instrument, said method comprising the steps of: sending one or more quality control specimens to a operator of the analytical instrument;

directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the one or more quality control specimens; analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument; and providing notice to an operator regarding the functional status of the analytical instrument.	directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the one or more quality control specimens; analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument; and providing notice to an operator regarding the functional status of the analytical instrument <u>wherein the control data is communicated to the analytical instrument by a machine readable label attached to the quality control specimen.</u>
Claim 19 (10/733542)	Claim 2 (6,748,337)
19. A method for providing quality control in an analytical instrument, said method comprising the steps of: sending one or more quality control specimens to a operator of the analytical instrument directly or indirectly communicating control data to the analytical instrument, wherein the control data includes acceptable operating standards analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument and providing notice to the operator regarding the functional status of the analytical instrument	2. A method for providing quality control in an analytical instrument, said method comprising the steps of: sending one or more quality control specimens to a operator of the analytical instrument directly or indirectly communicating control data to the analytical instrument, wherein the control data includes <u>characteristic values for the one or more quality control specimens</u> analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument and providing notice to the operator regarding the functional status of the analytical instrument wherein the control data is communicated to the analytical instrument by a machine readable medium supplied with the quality control specimen.



Claim 20 (10/733542)	Claim 9 (6,748,337)
<p>20. A quality control system for analytical instruments, said system comprising: one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen an analytical instrument, having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values means for evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values to determine a functional status of the analytical instrument; and means for notifying an operator regarding the functional status of the analytical instrument .</p>	<p>9. A quality control system for analytical instruments, said system comprising: one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen an analytical instrument, having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values means for evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values to determine a functional status of the analytical instrument <u>wherein the means for evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values does not require input from an operator means for notifying an operator regarding the functional status of the analytical instrument and means for selectively preventing the reporting of test results in the event the functional status of the analytical instrument is determined to be unacceptable</u></p>

**Conclusion**

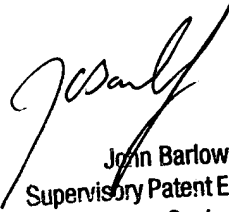
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Margery et al. (USPN 6,192,320) teaches an interactive remote sample analysis system, Bass et. Al (USPUB 2003/0064393 A1) teaches integrated systems and methods for diversity generation and screening, Marcus (USPUB 2002/0003210 A1) teaches a sampling and analysis of airborne particulate mater by glow discharge atomic emission and mass spectrometries.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditya S Bhat whose telephone number is 703-308-0332. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 703-308-3126. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-5841 for regular communications and 703-308-5841 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

Aditya Bhat  
December 7, 2004

  
John Barlow  
Supervisory Patent Examiner  
Technology Center 2800